

HEALTH SMART BABY- talc powder
Home Smart Products

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active Ingredient

Talc 100%

Purpose

Skin Protectant

Uses

For Babies: Use after every bath and diaper change to make your baby's skin soft and smooth. Helping to keep your baby happy and comfortable.

For Adults: Use after bath or shower to keep your skin fresh and comfortable. Helps eliminate friction to keep skin from becoming irritated.

WARNING

Warning

For external use only. Avoid contact with eyes discontinue if irritation develops.

Keep Out of Reach of Children

Children if swallowed get medical help or contact Poison Control Center right away.

Directions

Apply product liberally, as often as necessary

Storage

Store in a cool and dry place. Close tightly after use.

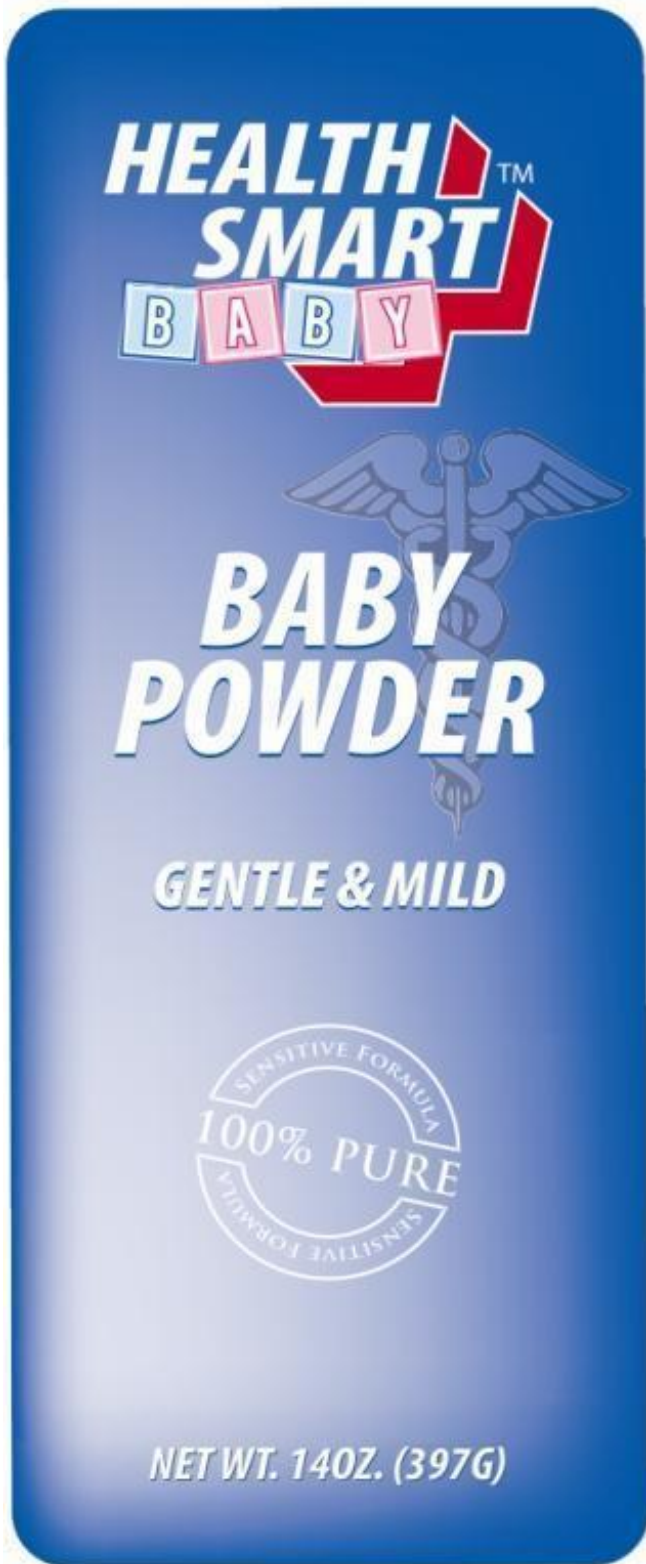
Inactive Ingredient

Fragrance

PRINCIPAL DISPLAY PANEL

Health Smart Baby Powder

NET WT. 14 OZ (397G)



HEALTH SMART BABY			
talc powder			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52862-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TALC (UNII: 7SEV7J4R1U) (TALC - UNII:7SEV7J4R1U)	TALC	1 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	0.001 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52862-010-13	57 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	
2	NDC:52862-010-14	113 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	
3	NDC:52862-010-15	397 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	
4	NDC:52862-010-16	624 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	
5	NDC:52862-010-17	680 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	
6	NDC:52862-010-18	737 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	12/19/2012	

Labeler - Home Smart Products (161872676)**Registrant** - Jell Pharmaceuticals Pvt. Ltd. (726025211)**Establishment**

Name	Address	ID/FEI	Business Operations
Jell Pharmaceuticals Pvt. Ltd.		726025211	manufacture(52862-010)

Revised: 8/2020

Home Smart Products